

Amendments to the Claims:

The listing of claims will replace all prior versions and listings, of claims in the application:

Listing of Claims:

Claims 1-11 (canceled)

Claim 12 (currently amended): A method for determining a 5-Fluorouracil-based chemotherapeutic regimen for treating a tumor in patient comprising:

- (a) obtaining a tumor sample from the patient;
- (b) fixing at least a portion of said tumor sample in paraffin to achieve a fixed and paraffin embedded (FPE) tumor tissue sample,
- (c) isolating mRNA from said FPE tumor tissue sample;
- (d) subjecting the mRNA isolated from said FPE tumor tissue to amplification using a pair of oligonucleotide primers SEQ ID NO: 1 and SEQ ID NO: 2 to obtain an amplified sample,
- (e) determining the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample;
- (f) comparing the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample with a predetermined threshold level for *DPD* expression;
- (g) determining a 5-Fluorouracil-based chemotherapeutic regimen for said patient based on the difference in amount of *DPD* mRNA in the amplified sample and the threshold level for *DPD* gene expression.

Claim 13 (previously presented): The method of claim 12, wherein said predetermined threshold level of *DPD* gene expression is about 2.0 to about 2.5 times that of an internal control gene expression level.

Claim 14 (previously presented): The method of claim 12 or 13, wherein said internal control gene is β -actin.

Claim 16 (previously presented): The method of claim 12 or 13, wherein the mRNA is isolated in the presence of an effective amount of chaotropic agent.

Claim 23 (currently amended): A method for determining a 5-Fluorouracil-based chemotherapeutic regimen for treating a tumor in a patient comprising:

- (a) obtaining a tumor sample from the tumor;
- (b) fixing at least a portion of said tumor sample in paraffin to achieve a fixed and paraffin embedded (FPE) tumor tissue sample,
- (c) isolating mRNA from said FPE tumor tissue sample;
- (d) subjecting the mRNA isolated from said FPE tumor tissue to amplification using a pair of oligonucleotide primers SEQ ID NO: 7 and SEQ ID NO: 8 to obtain an amplified sample;
- (e) determining the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample;
- (f) comparing the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample with a predetermined threshold level for *DPD* expression;
- (g) determining a 5-Fluorouracil-based chemotherapeutic regimen for said patient based on the difference in amount of *DPD* mRNA in the amplified sample and the threshold level for *DPD* gene expression.

Claim 24 (previously presented): The method of claim 23, wherein said predetermined threshold level of *DPD* gene expression is about 2.0 to about 2.5 times that of an internal control gene expression

level.

Claim 25 (previously presented): The method of claim 23 or 24, wherein said internal control gene is β -actin.

Claim 27 (currently amended): A method for determining a 5-Fluorouracil-based chemotherapeutic regimen for treating a tumor in patient comprising:

- (a) obtaining a tumor sample from the patient, and wherein said tumor sample is fixed and paraffin embedded (FPE);
- (b) isolating mRNA from said FPE tumor tissue sample, wherein said tumor sample is heated to a temperature in the range of ~~about~~ 50 to ~~about~~ 100°C;
- (c) subjecting the mRNA isolated from said FPE tumor tissue to amplification using a pair of oligonucleotide primers SEQ ID NO: 1 to obtain an amplified sample,
- (d) determining the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample;
- (e) comparing the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample with a predetermined threshold level for *DPD* expression;
- (f) determining a 5-Fluorouracil-based chemotherapeutic regimen for said patient based on the difference in amount of *DPD* mRNA in the amplified sample and the threshold level for *DPD* gene expression.

Claim 28 (previously presented): The method of claim 27, wherein said predetermined threshold level of *DPD* gene expression is about 2.0 to about 2.5 times that of an internal control gene expression level.

Claim 29 (previously presented): The method of claim 27 or 28, wherein said internal control gene is β -actin.

Claim 31 (previously presented): The method of claim 27 or 28, wherein the heating is in the presence of an effective amount of chaotropic agent.

Claim 32 (currently amended): A method for determining a 5-Fluorouracil-based chemotherapeutic regimen for treating a tumor in patient comprising:

- (a) obtaining a tumor tissue sample from the patient, and wherein said tumor tissue sample is fixed and paraffin embedded (FPE);
- (b) isolating mRNA from said FPE tumor tissue sample, wherein said tumor sample is heated to a temperature in the range of ~~about~~ 50 to ~~about~~ 100°C;
- (c) subjecting the mRNA isolated from said FPE tumor tissue sample to amplification using a pair of oligonucleotide primers SEQ ID NO: 7 and SEQ ID NO: 8 to obtain an amplified sample;
- (d) determining the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample;
- (e) comparing the amount of *Dihydropyrimidine Dehydrogenase (DPD)* mRNA in the amplified sample with a predetermined threshold level for *DPD* expression;
- (f) determining a 5-Fluorouracil-based chemotherapeutic regimen for said patient based on the difference in amount of *DPD* mRNA in the amplified sample and the threshold level for *DPD* gene expression.

Claim 33 (previously presented): The method of claim 32, wherein said internal control gene is β -actin.

Appl. No. 09/879,217
Amendment dated June 1, 2004
Reply to Office Action of March 29, 2004

Claim 34 (previously presented): The method of claim 27, wherein the heating is in the presence of an effective amount of chaotropic agent.